IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

JUDY ROMERO	§	
	§	
Plaintiff,	§	
	§	CIVIL ACTION NO. 1:03-cv-1367
v.	§	
	§	Judge Marcia A. Crone
WYETH PHARMACEUTICALS, INC.,	§	
and WYETH, INC.,	§	
	§	
Defendants.	§	

PLAINTIFF'S OPPOSITION TO
WYETH'S MOTION FOR PARTIAL SUMMARY JUDGMENT

This Court has already heard the same arguments in Defendants' motion, not quite a year ago, in the *Lea* case, and the facts of Mrs. Romero's case do not present any reason for this Court to come to a different conclusion here.[1] If anything, the facts of Mrs. Romero's case present an even stronger factual basis for again denying Defendant's motion in its entirety. Defendants, Wyeth Pharmaceuticals, Inc., and Wyeth, Inc. ("Wyeth"), cannot meet their burden of showing that there are no genuine issues of material fact present. For that reason, similar motions for summary judgment have been denied by every federal and state court faced with these issues. Again, this Court previously rejected the very same arguments, denying Wyeth's summary judgment motion on plaintiff's fraud, negligent misrepresentation, negligence, gross negligence, failure to warn, design defect and DTPA claims.[2] Accordingly, Wyeth's Motion should be denied.

[1] Ex. 1 – Order, *Lea v. Wyeth*, 10/28/11.
[2] Ex. 1 – Order, *Lea v. Wyeth*, 10/28/11.

I. PLAINTIFF'S RESPONSE TO WYETH'S UNDISPUTED MATERIAL FACTS

A. Plaintiff's Response to Wyeth's Undisputed Material Facts

1. Disputed insofar as the Food and Drug Administration ("FDA") found that Wyeth improperly "overemphasized" an osteoporosis benefit given the risks of E therapy.[3]

2. Undisputed

3. Undisputed

4. Undisputed

5. Undisputed

6. Disputed as incomplete. As reported in Wyeth's own summary of the 1990 Advisory Committee meeting, Dr. Barbara Hulka, Committee Chairperson, "clarified that the committee was not convened to determine whether or not HRT should be used nor are they to discuss the risk vs. benefit. They are confined to determine the possible association between breast and endometrial cancer and HRT."[4]

7. Undisputed.

8. Disputed, insofar as the advisory committee determined that there were insufficient data to distinguish between different estrogens or if the addition of a progesterone alters the risk of breast cancer.[5]

9. Disputed. According to Wyeth, the FDA Advisory Committee's 1991 inquiry "attempted to determine the actual risk of breast cancer recurrence with HRT and ERT, and whether this risk

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[3] Ex. 2 – PX 213 - Wyeth's August 14, 1992 internal correspondence characterizes the FDA's assessment of its Premarin advertisement "to be misleading in that it overemphasizes the impact of osteoporosis and fails to adequately address the risk of estrogen replacement therapy."

[4] Ex. 3 – PX 135 - The question posed to the committee was: "Is there sufficient evidence to conclude that unopposed ERT is associated with an increased risk of breast cancer in postmenopausal women?" Prior to this meeting, Dr. Barbara Hulka successfully petitioned Wyeth to fund a study that she would perform. Ex. 4 - July 2, 2007 Expert Report of Suzanne Parisian, M.D. at 39-40.

[5] Ex. 5 - Feb. 15, 2006 Report of Cheryl Blume, Ph. D., at 24.

is balanced by the recognized benefits of replacement therapy in menopause." The Committee agreed that the inquiry was "essentially asking for the results of clinical trials that have yet to be performed, and that the trials would have to be conducted before these answers could be provided."[6]

10. Undisputed.

11. Undisputed.

12. Undisputed.

13. Undisputed.

14. Disputed. Wyeth's characterization of the relative risk as "slightly higher" is argumentative, vague, and unsupported.

15. Disputed. The same article also indicates that "Relatively short-term combined estrogen plus progestin use increases incident breast cancers, which are diagnosed at a more advanced stage compared with placebo use, and also substantially increases the percentage of women with abnormal mammograms."[7]

16. Disputed. The WHI had a high drop-out rate (40%) as well as a significant cross-over rate of 10% (where placebo users started taking the drug but were still counted as placebo patients in the study) leading to an almost 50% contamination in the data.[8]

17. Disputed. The WHI study showed an increase in DCIS cases, just not enough to be statistically significant.[9]

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[6] Ex. 6 – PX 188 - Internal Wyeth memorandum from Mark J. Mariani to Stephen Sasson (March 17, 1992).

[7] Ex. 7 – PXML 2 - Chlebowski et al., *Influence of Estrogen Plus Progestin on Breast Cancer and Mammography in Healthy Postmenopausal Women*, 289 J. AM. MED. ASS'N. 3243 (2003).

[8] Ex. 8 - Expert report of Dr. Austin, 2/8/11 at p. 3; Ex. 9 – PXML 6016B - Santen, Colditz, *Postmenopausal Hormone Therapy: An Endocrine Society Scientific Statement*, J. OF CLINICAL ENDO & MET, 95, Supplement 1:S1-S66 (2010) at S 4.

18. Undisputed

19. Undisputed.

20. Undisputed.

21. Disputed, insofar as Defendant has not included the corresponding exhibit, inhibiting Plaintiff's ability to confirm or deny the referenced record.

22. Undisputed.

23. Undisputed.

24. Undisputed.

25. Undisputed

26. Undisputed.

27. Undisputed.

28. Undisputed.

29. Disputed. Using a Gail model calculation, Dr. Elizabeth Z. Naftalis concluded that Plaintiff was not at high-risk for developing breast cancer when placed on E+P.[10]

30. Undisputed.

31. Disputed. Plaintiff's testimony was that her decision to start taking E+P was based on her discussions with her prescribing physician.[11]

32. Disputed. Plaintiff testified that she trusts her doctors to discuss the risks and benefits of any treatment plan.

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[9] When the WHI investigators separately analyzed *in situ* cases in E+P users they found an elevated mean hazard ratio.

[10] Ex. 10 - Expert report of Dr. Naftalis, 4/4/11 at p. 42. "A lack of breast feeding some years ago however would not create a current source of hormones necessary to fuel the growth and development of a hormone dependent breast cancer." *Id*. at 32. "Oral contraceptives have not been shown to increase a woman's risk of menopausal breast cancer." *Id.* at 33. Ms. Romero has no family history of breast cancer. *Id*. at 34.

[11] Ex. 11 - Deposition of Judy Romero, 5/22/09 at 252: 13-253: 4.

33. Disputed. Plaintiff testified that, as of her deposition, she had not seen the warnings for Premphase in a "long time," adding that she always has "labels" with the medications she buys at the pharmacy.[12]

34. Undisputed.

35. Disputed. When asked if Plaintiff received package inserts with every prescription she receives, Plaintiff testified that she is sure that every medication comes with an insert and that she glances *through* the package inserts.[13]

36. Undisputed.

37. Disputed. Dr. Lal testified that she is not sure if she told her patients in the mid-1990s that E+P causes breast cancer.[14]

38. Undisputed.

39. Disputed as incomplete. Of the twenty-three pages within the "Hormone Replacement Therapy and Your Help" pamphlet, only one paragraph discusses breast cancer risk, indicating that "some studies" show such a risk in cases in which women used "estrogens" for "long periods of time" or "higher doses." The label indicates the risk of added progestins on the risk of breast cancer is unknown, with only some studies reporting a "moderately increased" risk, despite other studies not showing such a risk.[15]

40. Undisputed.

41. Undisputed.

42. Undisputed.

43. Undisputed.

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[12] *Id*. at 218: 18-219: 5.

[13] *Id*. at 265: 21-266: 23.

[14] Ex. 12 - Deposition of Dr. Radha Lal ("Dr. Lal dep.") 4/27/11 at 118: 5-9.

[15] Ex. 13 - Dr. Lal dep, Exh. 3 to the deposition.

44. Undisputed.

45. Undisputed.

46. Undisputed.

47. Undisputed.

48. Undisputed.

49. Undisputed.

B. Additional Facts Supporting Denial of Wyeth's Motion for Summary Judgment.

1. Wyeth's Fraudulent Representations about the Risks and Benefits of E+P.

Judy Romero started taking Premphase in 1996, later switching to Prempro (with both drugs containing the same active ingredients of conjugated equine estrogen and a progestin, or E+P), which she took until her diagnosis of hormone receptor-positive breast cancer in 2001. Throughout the time that plaintiff ingested E+P, the language contained within Wyeth's product labeling for Prempro and Premphase[16] regarding a risk of breast cancer remained substantially the same, reassuring physicians and users of the drugs that the breast cancer risk from E+P was unknown, no greater than the background rate and, at most, a minimal risk if used for more than ten years or at a high dose. Such statements were false when made and known by Wyeth to be false, and were also inaccurate based upon information that Wyeth could have known.

First, despite dozens of safety signals and red flags that breast cancer studies were needed to answer this safety issue, Wyeth never conducted a breast cancer study despite a $2 to $3 billion annual budget for research and development.[17] Multiple Wyeth medical doctors and

[16] While plaintiff used Premphase as well as Prempro, Wyeth focused their motion on the Prempro label and plaintiff will thus also reference that label. However, the arguments made here about the Prempro label are equally true about the Premphase label.

[17] Ex. 14 - Trial transcript from *Barton v. Wyeth*, 10/16/09PM at p. 131:6-10.

senior researchers confirmed that Wyeth never performed a long-term human study to determine the risk of breast cancer.[18] Dr. Marc Deitch, Wyeth's medical director and senior scientific advisor, testified that he could not recall "even a single study done by Wyeth that would answer the question about the connection between hormone replacement therapy and breast cancer."[19] Dr. Harold Marder, Wyeth's senior vice-president, global medical director and head of Global Medical Affairs, testified that he was not aware of "any study" done by Wyeth to "determine whether combination estrogen and progestin could cause cancer."[20] Dr. Pamela Cobb, director of Global Medical Affairs for Wyeth confirmed "Wyeth never did a breast cancer trial."[21]

Second, the Prempro warning from 1995 to 2002, even though it discusses estrogen only use and claims that the risk of E+P is "unknown," was intended to be a complete warning of the risks for E+P. Wyeth intended doctors to apply all of the provided information to both E+P and E, including the reassuring language that the majority of studies showed no increased risk of breast cancer. As Joseph Mahady, Senior Vice President of Wyeth, explains:

> "..[t]he first sentence after the warning, which says all the warnings below pertain to the use of the combination product. That's there for a purpose, and that's to tell them, while there may be some uncertainties, while there may be some unanswered questions, every single element of warning in here, whether it's described for estrogen alone or estrogen in combination, should be pertained to the use of the combination product. ***I think that's extremely clear***."[22]

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[18] Ex. 15 - PX 20820, Ex. 16 - PX 20821, Ex. 17 - PX 20822, Ex. 18 - PX 20824; Ex. 17 - Trial transcript from *Barton v. Wyeth*, 10/02/09PM at p. 51-58.

[19] Ex. 16 - PX 20821 at 3.

[20] Ex. 18 - PX 20824.

[21] Ex. 19 - Deposition of Pamela Cobb, 6/23/06 at p. 384:6-11.

[22] Ex. 20 - Deposition testimony, Joseph Mahady, 11/16/05 at p. 205:13-206:18 (emphasis added).

Wyeth's claim - that every sentence of this warning applies to E+P use - has been confirmed by numerous Wyeth executives.[23]

Consider each statement of this label and see how the warning provided only misleading and reassuring information to physicians and patients without revealing the truth about E+P.

Statement # 1 of the Prempro Label

> *"Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.0) in those women on estrogen replacement therapy taking* ***higher*** *doses, or in those taking lower doses for prolonged periods of time, especially* ***in excess of 10 years****."*[24]

By 1995, when Prempro was first introduced, Wyeth already knew a risk of breast cancer existed for *all* doses of E+P, not just higher doses. An October 17, 1994, an internal Wyeth memorandum summarized a discussion between Wyeth and one if it's most trusted consultants, Dr. Trudy Bush.[25] Dr. Bush told Wyeth in 1994 that data from a study by the National Cancer Institute showed an increased risk of breast cancer in women on **any** dose of E+P.[26] Wyeth also knew that a risk of breast cancer was associated with a far shorter duration of use than ten years. In August, 1989, the Bergkvist study, published in the *New England Journal of Medicine*, reported a 4.4 relative risk of breast cancer for six years use of E+P. Importantly, this study

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[23] Ex. 21 - Trial testimony, Dr. Ginger Constantine, Wyeth's Vice President of Clinical Research and Development, from *Reeves v. Wyeth*, 9/9/06 at p. 3318:22-3319:19. (Doctor would "obviously" apply the language of the Prempro label that the risk is seen with "taking higher doses than those taking lower doses for prolonged periods of time, especially in excess of ten years" to Prempro because of "this language up here that the warnings below pertain to Prempro."); Ex. 22 - Trial testimony, Dr. Marc Deitch, Wyeth's senior vice president for medical affairs and medical director, from *Nelson II v. Wyeth*, 1/22/07PM at p. 33:17-35:4 ("'Everything' in the Prempro breast cancer warning section "refers to combination therapy according to the labeling.").

[24] Emphasis added.

[25] Ex. 23 - PX 219 (Dr. Bush consulted on proposed rewrite of label); Ex. 24 - PX 341 (Dr. Bush is identified as an "advocate" who Wyeth intends to utilize as a "potential speaker for media").

[26] Ex. 25 - PX 8638.

reported an increase in risk after just two years of use.[27] Wyeth's immediate reaction in 1989 was to have the Bergkvist study's methodology analyzed. Wyeth's head scientist reported back that "[w]ell accepted methods of statistical analysis and techniques for controlling for bias and confounders are employed."[28] But Wyeth did not include that information in its label. Even worse, Wyeth directed its sales representatives to not discuss this article with prescribing physicians stating, "[u]nder no circumstances should you initiate discussions concerning this study."[29]

In 1995, a world-renowned breast cancer researcher, Dr. Graham Colditz, published an article confirming an increased risk for current E+P users after just five years of use.[30] This article was based upon data generated by the Nurse's Health Study, a study that Wyeth's general causation expert Dr. Lewis Chodosh agrees is "one of the best prospective studies, longitudinal studies available."[31] Wyeth's expert also confirms that Dr. Colditz is a "very-well-known" and "highly respected" epidemiologist[32] and a "thought leader" in his field.[33] Dr. Colditz's punchline conclusion from this article was that there was a "significant increase in the risks of breast cancer and of death due to breast cancer among women over 55 who are currently taking hormones and who have used hormones for more than 5 years."[34]

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27 Ex. 26 - PX ML 600.

28 Ex. 27 - PX 1428.

29 Ex. 28 - PX 114.

30 Ex. 29 - PX ML 3.

31 Ex. 30 - Trial testimony, Wyeth's causation expert, Dr. Chodosh, *Reeves v. Wyeth*, 9/7/06 at p. 2817-2818.

32 Ex. 31 - Trial testimony, Wyeth's general causation expert, Dr. Chodosh, *Rowatt v. Wyeth*, 10/3/07 at p. 4393; Ex. 32 - Trial testimony, Dr. Chodosh, *Daniel v. Wyeth*, 1/19/07 at p. 51.

33 Ex. 33 - Trial testimony, Dr. Deborah Lyon, *Singleton v. Wyeth*, 2/16/10 at p. 27-28.

34 Ex. 29 - PX ML 3 at p. 4.

Not only did Wyeth not include that information in its label, Wyeth's reaction to Dr. Colditz's paper went beyond concealment.[35] Wyeth actually misrepresented the Colditz results to doctors. Wyeth instigated a campaign to minimize the impact of this article so its alarming data did not dissuade doctors and patients from using Wyeth's drug. Wyeth's management met with its public relations consultant, Burson Marstellar, multiple times to "refine" its plan[36] and "reconfirm" its strategy[37] to "shift" the media's focus away from this article and to "undermine/cast doubt on validity of data by raising concerns."[38] On June 2, 1995, Wyeth's PR group proposed that Wyeth send a "*Dear Doctor*" letter to every prescriber containing a quote by "an opinion leader/physician, e.g., Leon Speroff, Trudy Bush, etc. to help balance the data."[39] The "suggested message" for this letter was to be that there was "no definitive answer" regarding hormone drugs and breast cancer "after 40 observational studies."[40] One week later, Wyeth did just that and wrote every prescribing physician.[41] In that letter, Wyeth represented that "Leon Speroff, M.D., a leading research expert from Oregon Health Sciences University" had commented at a meeting in March that "despite some 40 observational studies, no consistent data linking estrogen use and breast cancer exist." Wyeth did not reveal that Dr. Speroff was a paid consultant to Wyeth or that this alleged quote – designed to reassure physicians – had actually been created by Wyeth and its PR consultants seven days earlier.

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35 To counter the Colditz article, Wyeth also used its "relationship with the editor" to publish a presentation by another physician, Dr. Wiles, which reassured physicians that hormone drugs were actually "anti-promoters of breast cancer" and increased survival rate, facts in direct opposition to Dr. Colditz's data from the well-respected Nurse's Health Study. Ex. 34 - PX 1585. Wyeth handed copies of this paper out to its sales representatives for distribution to physicians. Ex. 35 - PX890E.

36 Ex. 36 - PX 20991 at p. 1.

37 Ex. 37 - PX 8744A at p. 1.

38 Ex. 36 - PX 20991 at p. 2.

39 Ex. 37 - PX 8744A at p. 1.

40 Ex. 37 - PX 8744A at p. 2.

41 Ex. 38 - PX 1579.

In 1997, an international research group called the Collaborative Group published a review of the worldwide literature on hormone drugs and breast cancer.[42] The Collaborative Group concluded that E+P users, after only a few years of use, were at an increased risk for breast cancer and that the risk went up with every year of drug use. This would have been important information for a woman like Judy Romero who used E+P for approximately 5 years. Wyeth reacted, yet again, by telling all of its sales representatives to conceal the article from physicians they solicited.[43] Wyeth told its sales representatives: "Do not raise these articles with your doctors," but rather, emphasize that "the long term benefits of HRT still by far outweigh any risks."[44] Even though, under FDA regulations, Wyeth's agents must use "fair balance" in all discussions with doctors and spend equal time discussing risks as they do discussing benefits,[45] Wyeth strictly ordered its sales reps in 1997 to "not engage physicians in a discussion" about the article but instead "continue to focus your presentation on the benefits of HRT."[46]

To overshadow the findings of the Collaborative Group, Wyeth instigated and funded a Continuing Medical Education program called "Myths & Misperceptions." To receive some of the $12 million in allocated grant money for this program, an organization had to first confirm a "willingness to take the position that hormone therapy does not cause breast cancer."[47] Wyeth's intent was to change patients' perspectives so women would not believe that E+P caused breast cancer.[48] The "Myths & Misperceptions" educational program also produced a newsletter for physicians in which Wyeth claimed "there is almost uniform agreement" that adding P to E does

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42 Ex. 39 - PX ML 22

43 Ex. 40 - PX 20957.

44 Ex. 40 - PX 20957.

45 Ex. 41 - Deposition testimony, Wyeth's Vice President of Marketing, Steve Strickland, 9/9/05 at p. 623:21-625:5

46 Ex. 42 - PX 8306.

47 Ex. 43 - PX 7422A.

48 Ex. 44 - PX5677.

not cause an increased breast cancer risk.[49] But, just three months earlier, an oncology medical journal published an article in which the authors concluded that postmenopausal hormone therapy caused breast cancer and the link was "unequivocal."[50] Although Wyeth knew of the article and other concurring opinions, it purposefully misrepresented to prescribing physicians that there was "almost uniform agreement" of no increased breast cancer risk.

In early 2000, two papers were published in sequential months - the Ross and Schairer studies.[51] These studies showed a real difference between the risk of E alone and E+P. This was important data because Wyeth trained its sales representatives to reassure doctors that the breast cancer risk for E and E+P were the same. As Brett Hendricks, a former sales representative trainer for Wyeth explains, Wyeth trained its sales reps to tell doctors that the risk for estrogen alone and E+P were "identical."[52] But the Schairer paper showed a doubling of the risk of breast cancer for some E+P users after only four years of use, a very different risk than for E alone.[53]

Wyeth was understandably concerned by these two new articles and immediately formed the "***Breast Cancer Containment*** and Communication" task force.[54] Wyeth recognized that these studies could have a "labeling impact."[55] As internal memoranda explained, the "context" for this committee was that:

* A second article in a month associated HRT use with increased breast cancer risk;

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49 Ex. 45 - PX427.

50 Ex. 46 - PX ML 3862.

51 Ex. 47 - PX ML 98; Ex. 48 - PX ML 63.

52 Ex. 49 - Trial testimony of Brett Hendricks (1/22/10AM), *Singleton v. Wyeth*, p. 79:14-88:7 (Mr. Hendricks confirms that Wyeth trained its sales representatives that E+P should be used long-term, prescribed for unproven and unapproved heart and brain benefit, that these drugs did not cause breast cancer and might even be protective against the development of breast cancer and that E and E+P had identical risks, if any).

53 Ex. 48 - PX ML 63 at p. 5, Table 2.

54 Ex. 50 - PX 519 (emphasis added).

55 Ex. 50 - PX 519 at p. 2.

* The trend for women to demand to be removed from therapy or decline to start therapy would continue;
* The accumulating weight of "evidence" creates uncertainty / inaction among health care professionals.[56]

At any point in time, Wyeth could have strengthened its Prempro label immediately without any prodding or approval from the FDA. Under the FDA regulations of the time, a drug company could strengthen its label pursuant to the "changes being effected" ("CBE") regulation.[57] This regulation permitted a manufacturer to "add or strengthen a contraindication, warning, precaution, or adverse reaction" for a drug at any time, without prior approval.[58] In fact, the manufacturer was obliged to revise its label "to include a warning as soon as there [was] reasonable evidence of an association of a serious hazard with [its] drug; a causal relationship need not have been proved."[59] But Wyeth chose not to update its label year after year. Instead, Wyeth issued a "*Dear Doctor*" letter in early 2000 to specifically reassure physicians.[60] This letter told doctors that the Ross and Schairer studies showed risks "consistent with, if not lower than, preceding studies" and were "consistent with what is reported in labeling for both ERT and HRT."[61] Wyeth stated that "the risk data reported in these and other studies over the preceding 25 years are conflicting and inconclusive"[62] and that more studies were needed to get a real answer on the breast cancer issue. Even worse, Wyeth assured doctors that "the available evidence does not warrant significant changes in current medical practice."[63]

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56 Ex. 50 - PX 519 at p. 1.
57 *See* 21 C.F.R. § 314.70(c)(6)(iii)(A).
58 *Id.*
59 21 C.F.R. 201.80(e).
60 Ex. 51 - PX 5775 – Wyeth's "Dear Doctor" letter.
61 Ex. 51 - PX 5775 at p. 1.
62 Ex. 51 - PX 5775 at p. 2.
63 *Id.*

Wyeth encouraged doctors to counsel their patients since "many women may be confused, if not frightened, by the recent media coverage. Therefore, those already on therapy and those considering it will need education and reassurance from you." Wyeth told physicians to reinforce the long-term benefits of hormone therapy including that "ERT and HRT protect against osteoporosis and are associated with a reduced risk for developing heart disease. Clearly, the most reassuring message was that these long-term benefits alone far outweigh the potential increased risks reported in the studies."[64] These sentences are particularly troubling since they involve off-label promotion for an unproven benefit (heart benefit) and were in direct violation of FDA regulations. Over the years, the FDA had admonished Wyeth repeatedly to not promote hormone therapy for a heart benefit. And just a few months earlier, Wyeth had specifically promised the FDA that it would never again promote its drugs for such a benefit.[65] Despite that assurance, Wyeth engaged in precisely the prohibited conduct in this letter, telling doctors that the heart benefit outweighed any illusory and unconfirmed breast cancer risk.

Even worse, Wyeth attached to the back of this "*Dear Doctor*" letter a chart that purportedly represented the breast cancer statistics from the studies looking at both estrogen alone (ERT) and E+P (HRT).[66] On this chart, Wyeth included information from the 1989 Bergkvist study but, despite the title of the chart suggesting that it provided both ERT and HRT data, the chart reported only the estrogen (ERT) statistic from that study. In reality, the Bergkvist study showed an E+P relative risk of 4.4 that would have been literally off Wyeth's chart.[67] Wyeth did not include it, leaving a very different and calming impression for doctors.

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64 Ex. 51 - PX 5775 at p. 3.

65 Ex. 52 - PX 470 at p. 3 (Wyeth agreed to "refrain" from any cardiac representations).

66 Ex. 51 - PX 5775 at p. 5.

67 Ex. 26 - PX ML 600.

In conclusion, until 2002, Wyeth misrepresented the risk of breast cancer for users at any dose and for less than ten years of use, deliberately representing that E+P had no risk at all or a lower risk than it actually did.

Statement # 2 of the Prempro Label

> *"The majority of studies however, have not shown an association in women who have ever used estrogen replacement therapy. The effect of added progestins on the risk of breast cancer is unknown, although a moderately increased risk in taking combination estrogen/progestin therapy has been reported. Other studies have not shown this relationship."*

Wyeth knew these statements were false. Wyeth knew that the authors of the majority of studies conducted before 2002 reported an increased risk of breast cancer in E+P users. In fact, three times as many pre-WHI study authors discussed an increased risk. There were 45 studies that considered E+P (in some way) and breast cancer in this time frame. [68] Of these, 32 authors discussed an increased risk. And among the review articles, four of five found a risk of breast cancer. The only one that did not – a review by Dr. Trudy Bush - was ghostwritten by Wyeth.[69] Researcher after researcher described an increased risk of breast cancer for E+P users and that the risk for E+P was higher than for E alone.

Statement # 3 of the Prempro Label

> *"In a one year clinical trial of Prempro, Premphase and Premarin alone, 5 new cases of breast cancer were detected among 1377 women who received the combination treatments, while no new cases were detected among 347 women who received Premarin alone. The overall incidence of breast cancer in this clinical trial does not exceed that expected in the general population."*

These statements are misleading since: (a) Wyeth knew that this one year study was not designed or powered to detect an increased breast cancer incidence. In 1992, Wyeth confirmed

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[68] Ex. 53 - See attached list which provides an analysis of the studies conducted and shows that the majority reported an increased breast cancer risk with E+P users.

[69] Ex. 54 - PX 8155B.

for the FDA that "an evaluation of breast cancer risk would not be a subject of evaluation" in this study.[70] (b) When Wyeth's own investigator did a causality assessment on these new breast cancers, the investigator concluded that one of the new cases of breast cancer was possibly caused by the drug, and after only one year of use.[71] Not only did Wyeth not include that fact but rather Wyeth continued to tell doctors that the increased risk was only for users of more than ten years. (c) Despite the reassuring sentence indicating no greater risk than the expected background rate, [72] Wyeth's own analysis actually showed that the incidence of breast cancer in this study was one-third higher than the incidence in the general population.[73]

Statement # 4 of the Prempro Label

> *"In addition to the one-year Pivotal Trial, the 1997 Prempro label discusses the PEPI (Postmenopausal Estrogen Progestin Intervention) study. The label states:*

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70 Ex. 55 - PX 20963 - at p.2; Ex. 56 - PX 288 - FDA Medical Officer's Review at p. 14.

71 Ex. 57 - PX285 at 26-27.

72 In the past, Wyeth claims in its reply brief that an FDA officer, Dr. Bruce Stadel, was the person who first summarized the clinical trial data to show no increase in risk above the background rate. But that representation is inaccurate. On December 15, 1994, Wyeth sent the FDA some additional information that had been requested by Dr. Stadel including data on Wyeth's clinical trial. In that filing, Wyeth represented to Dr. Stadel that the study results showed that "the breast cancer findings for women who participated in study 71 3-B-300, -301 are generally consistent with the expected background incidence rate." Two weeks later, on December 29, 1994, Dr. Stadel copied that assessment by Wyeth into a memo. There is no evidence that Dr. Stadel did any independent analysis of the data or anything more than just accepting as true what Wyeth had told him.

73 Ex. 58 - PX830 - at 18 (Overall, the incidence rate rate was 0.41 per 100 PY in the E+P arm and 0.29 per 100 PY from the SEER database placebo group (the background rate), giving an increase is risk of 1.47). When five **new** cases of breast cancer developed in the E+P group after just one year of drug, the FDA became alarmed about this "clustering of cases." Ex. 56 - PX 288 - FDA Medical Officer's Review at p. 56. After analyzing the data, the FDA told Wyeth to include in the Prempro label that five ***new*** cases of breast cancer "***developed***" in the E+P arm. Ex. 59 - PX 8014A - FDA communication with Wyeth re: Prempro label, at p. 4 (emphasis added). This statement would warn doctors that E+P could cause the development of new breast cancers after far less than ten years of exposure, indeed after just one year of drug use. Wyeth refused. Instead, Wyeth changed the proposed language to read "5 new cases of breast cancer were ***detected***" in the E+P arm. Ex. 60 - PX 8014B - Wyeth's response to FDA's proposed language (emphasis added).

> *In the three year clinical Postmenopausal Estrogen Progestin Intervention (PEPI) trial of 875 women to assess differences among placebo, unopposed Premarin, and three different combination hormone therapy regimens, one(1) new case of breast cancer was detected in the placebo group (n=174), one in the Premarin alone group (n=175),* ***none in the continuous Premarin plus continuous medroxyprogesterone acetate group (n=174)*** *and two (2) in the continuous Premarin plus cyclic medroxyprogesterone acetate group (n=174)." (*emphasis added).

This statement reassured physicians that the PEPI trial did not show an increased breast cancer risk with E+P. But Wyeth knew that the PEPI trial could provide no answers about this risk since the PEPI trial was not designed to provide breast cancer information. Nor was it powerful enough to detect such a risk. An internal Wyeth memorandum acknowledges both facts.[74] Wyeth's own executives admit that the PEPI trial was not designed with the power necessary to answer the breast cancer issue, yet the company included the results in the Prempro label to provide additional comfort for doctors.[75]

As shown above, the Prempro label was inaccurate and misleading on several fronts. But, in addition, Wyeth did not include information in this label regarding the heightened risk of breast cancer for specific subpopulations of E+P users, including thinner women. Multiple studies showed that thin women were at a heightened risk for developing breast cancer if they ingested E+P. Wyeth was well aware of these findings but never included this information in the Prempro label in the United States.[76] Wyeth did include this information in its E+P label for Europe.[77] Judy Romero is a very thin woman.

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74 Ex. 61 - PX 20941.

75 Ex. 61 - PX 20941.

76 Ex. 62 - Trial testimony, Dr. Suzanne Parisian, *Torkie-Tork v. Wyeth*, 11/22/10 at 51:3-53:7; 59:1-18.

77 Ex. 63 - PX 811 at p. 6 (Increased risk was found mostly for women with a lean or normal body build rather than for obese women); Ex. 64 - Trial testimony of Dr. Blume in *Daniel v. Wyeth*, 1/10/07 PM at p. 22-44.

2. Wyeth Refused to Update Its Prempro Label, Even When the FDA Ordered Them to Do So

The FDA planned to modify much of the equivocal language, remove the statement that the "effect of added progestins on the risk of breast cancer is unknown" and replace it with reference to epidemiological studies which confirmed that adding P to E increased the breast cancer risk by 25-40%.[78] The FDA ordered Wyeth to strengthen its label within 90 days.[79] Wyeth's response concealed study data critical to this assessment from the agency, containing a label change language that was watered down to the point of being even more reassuring.[80] By August 11, 2000, Wyeth mailed its final version to the FDA, having deleted the 4.42 relative risk number as well as any reference to the Gapstur study,[81] even from the general reference list.[82] Wyeth cherry-picked the data it wanted the FDA to have, deleting data that fully supported the FDA's proposed revisions, if not requiring even stronger warnings.

Wyeth also misrepresented to the FDA that its clinical trial on E+P reflected an incidence of breast cancer that was no different than the background rate. Wyeth was then successful at getting this reassuring language included in the breast cancer "warnings" section of its label for Prempro. Yet, Wyeth's own assessment confirmed that the E+P users in this study had a 47% increased risk of developing breast cancer than the incidence of breast cancer in the general

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78 Ex. 65 - PX 20878.

79 Ex. 66 - PX 20876.

80 Ex. 67 - PX 560 - at p. 1.

81 But, importantly, in the draft response, Wyeth proposed to highlight to the FDA an alarming finding by Dr. Gapstur that E+P conveyed a 4.42 relative risk for breast cancer with use of less than five years. Ex. 67 - PX 560 - at p. 21 (Table 9). This 4.42 relative risk number came from the published Gapstur study. Ex. 68 - PX ML 866 - at p. 1. While Wyeth had sent a copy of the Gapstur study to the FDA along with other published studies as part of a regular and required quarterly filing, Wyeth had never drawn the FDA's attention to this particular result. In its proposed response, Wyeth felt that it was important enough to highlight it in a specific table.

82 Ex. 69 - PX 1659A - at p. 5 (reference list) and all attached tables.

population, as shown by the SEER data.[83] Wyeth falsely represented the results of this study, again identifying a lower risk than the product actually had.

Wyeth enlisted Dr. Trudy Bush, to sway the FDA. Dr. Bush had long been a spokesperson Wyeth called upon to defend its drug at every turn.[84] On September 26, 2000, Bush wrote the FDA[85] without disclosing her financial relationship with Wyeth, claiming the label changes were confusing and might "frighten" women. On November 7, 2000, several days after the FDA's 90-day deadline for the mandated label change, Arnold & Porter wrote the FDA on Wyeth's behalf, chastising the FDA for failing to consult with Wyeth before issuing a label change. Wyeth's lawyer demanded the FDA withdraw its deadline.[86] The FDA did not relent.[87]

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[83] Ex. 70 - PX 830 - at 18 (Overall, the incidence rate was 0.41 per 100 patient years in E+P users and 0.29 per 100 patient years from the SEER database placebo group giving a SJR=1.47(9500 CI, 0.47-3.43) (See Table 5, Appendix II)).

[84] Ex. 71 - PX 8022A at p. 3; Ex. 72 - Trial testimony, Justin Victoria, *Reeves v. Wyeth,* 9/6/06, at p. 2483:8-10 (Bush was a long-standing advisor).

[85] Ex. 73 - PX 20879 at p. 1-2.

[86] Ex. 74 - PX 10425 at p. 1-2.

[87] Wyeth will likely claim in its reply brief that, on February 21, 2001, the FDA approved Wyeth's proposed edits to the Prempro label. This claim is deceptive at best – a blatant misstatement at worst. In its past briefing on the topic, Wyeth failed to include the attachment to that document. That is because the attachment confirms that the FDA demanded in 2001 that Wyeth implement precisely the breast cancer warnings that it had ordered the company to implement in August of the previous year. Ex. 75 - PX 6766 at p. 13-14. Also, So, while the FDA approved some of Wyeth's changes to other parts of the label, it insisted that Wyeth implement the breast cancer warnings exactly as ordered in August, 2000. Plus, as the United States Court of Appeals for the Eighth Circuit in *Scroggin v. Wyeth* explained, Wyeth's internal documents cannot be "rebutted or characterized by" witnesses as the jury "could have concluded that the documents spoke for themselves and rejected Wyeth's self-interested explanation. *In re Prempro Prods. Liab. Litig. (Scroggin v. Wyeth),* 586 F.3d 547, 573 (8th Cir. 2009), *cert. denied*, 130 S. Ct. 3467 (U.S. June 21, 2010). By June, 2002, one month before the WHI results, the FDA was still demanding the same stronger breast cancer warnings from Wyeth. Ex. 76 - PX 21109 - at p. 15-16. Contrary to Wyeth's claim otherwise, the FDA never relented on its breast cancer warning demand. The FDA ordered Wyeth to change its label to warn that the addition of P to E may increase the breast cancer risk by 24 to 40 percent. That is a far cry from a label that says the effect of adding progestins is unknown. And the FDA's terminology deleted much of the equivocal language Wyeth had fought so hard to secure. Wyeth's spin on the breast cancer data in its Prempro label is fraud, pure and simple.

3. Intent to Deceive: Wyeth's Deceptive Labeling Was Part of a Strategy of Fraudulent Concealment.

The events below establish Wyeth's intent to conceal the actual breast cancer risk from **all** physicians and their patients (including Judy Romero and her prescribing physician), an intent that was successful. Wyeth knew that they had an obligation to disclose any information they received about an adverse effect of their drug. Indeed, the FDA specifically told Wyeth so in 1975. As Premarin sales began to rise in the late 1960s, so did the incidence of endometrial (uterine) cancer. In 1975, the connection between increased use of estrogen alone and endometrial cancer was confirmed by two independent research groups. In December of 1975, Wyeth attended a FDA advisory committee meeting where this link was discussed in detail.[88] Despite this, Wyeth immediately disseminated a "*Dear Doctor*" letter, disputing that its drug was linked to the cancer epidemic and claiming that cancer was too complicated to assess such blame.[89]

The FDA was outraged, scolding Wyeth days later that the letter had "incensed [sic] the FDA at all levels, including the Commissioner of Food and Drugs."[90] The FDA told Wyeth that it expected the drug company to formulate "a sound medical and scientific response to this new information,"[91] not to issue a letter that "misrepresents the scientific findings as published in the literature."[92] Wyeth knew that to react to adverse cancer information with concealment and subterfuge would mislead physicians. Yet, this is exactly what Wyeth did.

Wyeth concealed and suppressed the Colditz study on the breast cancer risk. In 1990, Dr. Graham Colditz, a world-renowned epidemiologist on breast cancer, planned to present findings

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88 Ex. 77 – PX 21; Ex. 78 – PX 24.

89 Ex. 79 – PX 22 at 1.

90 Ex. 78 – PX 24 at 1

91 Ex. 78 – PX 24 at 2.

92 The reference in the memo is to "Ayerst" but Wyeth and Ayerst are the same company.

on hormone drugs and breast cancer at a scientific meeting. Wyeth did not respond by arranging to incorporate Dr. Colditz's findings into its label or a "*Dear Doctor*" letter. Nor did Wyeth independently analyze the data. Instead, Wyeth arranged to have spokespeople at the meeting to counteract any negative press coverage and to assemble a press kit to distract participants and the press from the risks of HT by shifting attention to its purported benefits, most of which were illusory, off-label and illegal to promote.[93]

Wyeth concealed and misrepresented the findings of Dr. Steven Cummings on the breast cancer risk of E+P. Dr. Steve Cummings' work involved a 10-year prospective study of older women, sponsored by the National Institutes of Health. The study results, revealed in 1996, showed that a woman's bone mineral density affected her chance of developing breast cancer. Since E+P was being prescribed to prevent osteoporosis, Dr. Cummings concluded that "the risk of breast cancer associated with HT may have been substantially underestimated."[94] Wyeth admitted this study could call into question previous information given to doctors by Wyeth.

Such an important study with important results should have led to immediate dissemination of the information with new warnings. Instead, Wyeth acted to conceal and misrepresent the findings. First, Wyeth established a Breast Cancer Working Group led by executive Jeff Buchalter who distributed the Cummings abstract to the group with a memo warning: "Please keep this confidential -- Do not discuss w/ anyone outside of W-A [Wyeth-Ayerst]" (emphasis in original).[95] In a handwritten document relating to the Cummings memo,

93 Ex. 80 - PX1265 at 1-2.
94 Ex. 81 - PX346 at 1.
95 Ex. 82 - PX348.

Buchalter wrote: "Dismiss/Distract" after outlining Wyeth's strategy to avoid bad press: "Keep US press busy."[96]

Wyeth's breast cancer task force followed Buchalter's directive. The strategies it adopted for concealing the Cummings findings included: encouraging third-party allies to dismiss the data, concealing and downplaying the study, creating press material to counteract and discredit the data and retaining spokespeople to counterbalance the breast cancer risk, again with the illegal promotion of illusory, off-label benefits.[97]

Wyeth concealed evidence of the breast cancer risk of estrogen extracted from horse urine. Dr. T.H. Lippert of Germany reported that the majority of studies showing a breast cancer risk from hormone therapy involved Wyeth's horse urine estrogen (Premarin).[98] In discussions over how to respond to the Lippert article, Wyeth's vice-president for regulatory affairs, Justin Victoria, decided on concealment, or to use his words, "letting sleeping dogs lie." He warned that Wyeth should avoid any discussion of the composition of its product.[99]

Wyeth misrepresented the breast cancer risk, and concealed its involvement, in ghostwriting articles. Wyeth created a Publication Plan Committee to spearhead the "ghostwriting" of medical articles that would then be published under an independent doctor's name. Doctors who read the ghostwritten articles would have no idea that Wyeth had generated the concept for the article, paid a technical writer to write it, hunted for a physician to put his name to it and even paid the postage for that doctor to mail the completed transcript to the medical journal.[100] During one period, Wyeth was tracking as many as 51 such ghostwritten

96 Ex. 83 – PX 349.
97 Ex. 24 – PX 341; Ex. 84 – PX 347 at 2.
98 Ex. 85 – PXML 8000.
99 Ex. 86 – PX 506.
100 Ex. 87 – PX 950W.

articles.[101] These articles downplayed the breast cancer risk and encouraged use of E+P for unproven and illegal heart and brain benefits. At one point, Wyeth's president demanded that Wyeth's Publication Committee increase the number of publications favorable to hormone therapy so as to publish as least one positive piece per month.[102] These articles polluted the scientific literature that doctors relied upon in forming their opinions and Wyeth deliberately concealed its involvement in the ghostwritten articles.

Wyeth misrepresented and concealed the breast cancer risk through multiple media. For instance, Wyeth's promotional literature deliberately misrepresented the breast cancer risk. Promotional materials actually stated that women who use hormone therapy have no greater breast cancer risk than women who do not.[103] And material left with Wyeth's sales representatives falsely stated and warranted that women on hormone therapy have no greater risk than women not on the drug.[104]

4. The Effect of Wyeth's Fraud on Plaintiff's Physician.

The testimony of plaintiff's prescribing physicians, Dr. Eberhard Lotze and Dr. Radha Lal, demonstrate that, had either doctor known the true risks and absence of some of the purported benefits of hormone therapy for Mrs. Romero, neither would have prescribed E+P for her at the same dose or duration and both would have provided her with more definite warnings about the increased risk of breast cancer from hormone therapy.

To begin with, Dr. Lotze, who prescribed plaintiff E+P the longest, testified that drug companies are obligated to provide accurate information about risks and benefits,[105] and to not

101 Ex. 88 - PX8155G.
102 Ex. 89 - PX954.
103 Ex. 90 - PX21016.
104 Ex. 91 - PX20258 at 32.
105 Ex. 92 - Deposition of Dr. Lotze, 4/26/11 at p. 116: 20-117: 2.

do so would be inappropriate,[106] as he relies on the information provided by drug companies as a source of information. In addition to "drug detail people," Dr. Lotze would also review medical journals[107] and the Physicians' Desk Reference (PDR), as well as the label and package insert itself, to keep informed of the "risks and complications or indications" of medications he was prescribing.[108]

Dr. Lotze relied on sales representatives in forming his risk-benefit analysis of a drug, explaining that "certainly the drug detail people played no small role in keeping us educated as to what's current and what's new.[109] As Dr. Lotze testified, "we all thought, and we all counseled our patients, '[E+P] probably helps the heart.'"[110] In addition to the believed cardiac benefit, Dr. Lotze also understood E+P to carry a mental or Alzheimer's prevention benefit at the time he prescribed E+P to plaintiff.[111] As Dr. Lotze explained of the purported mental benefit, "we generally used that in our counsel, yes." In fact, Dr. Lotze considered both benefits as a part of his entire risk-benefit assessment for E+P.[112]

Dr. Lotze was aware of many more off-label benefits. Reviewing a Wyeth marketing piece entitled "Menopause Isn't Gone in a Flash," Dr. Lotze characterized the piece's listing of Alzheimer's disease, vision problems, tooth loss, heart disease, colon cancer, urogenital problems and osteoporosis as consistent with his understanding prior to WHI that E+P would benefit women by creating heart protection, helping their teeth, vision problems, memory, colon

106 *Id*. at 118: 16-20.
107 *Id*. at 115: 5-116: 14-16.
108 *Id*. at 37:15-22 and 120: 9-21.
109 *Id*. at 112: 9-19.
110 *Id*. at 125:12-21.
111 *Id*. at 127: 23-128:3.
112 *Id*. at 127: 8-21 and 128:4-9.

health and preventing osteoporosis.[113] As he explained, this "was a general litany that we believed back then."[114]

Like Dr. Lotze, Dr. Lal testified that she relied on various sources of information from drug manufacturers when making the decision to prescribe a drug, including discussions with sales representatives, leave-behind materials from sales representatives,[115] and the label and package insert information published in the Physicians' Desk Reference ("PDR")[116] as well as medical journals.[117] Dr. Lal expressly stated that she relies on drug companies to provide true and accurate information about the risks and benefits of its drugs when assessing those drugs and discussing the same drugs with his patients.[118]

Dr. Lal was similarly aware of the purported cardiac benefit of E+P that was perpetuated by Wyeth's marketing materials.[119] Although Dr. Lal testified that she would not have prescribed E+P solely for the cardiac benefits,[120] she also testified that sales representatives would leave booklets behind and that Dr. Lal would rely on "these sources of information to get a global understanding or full picture of hormone replacement therapy in 1996 and before."[121]

In one instance, Wyeth sales representative Donald C. Williams, II, who called on Dr. Lal, testified that he remembered seeing the Wyeth marketing piece, entitled, "Consider the

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113 *Id*. at 164: 7-2.

114 *Id*.

115 Ex. 12 - Deposition of Dr. Lal, 4/27/11 at 162: 18-23 and 163: 1-7. Dr. Lal testified that prior to 1996, sales representatives were a source of information about Premphase and Prempro. *Id.* at 158: 15-18.

116 *Id*., at 71: 6-72: 3.

117 *Id.* at 157: 10-20.

118 *Id*. at 163: 8-164: 20.

119 *Id*. at 167: 8-19.

120 *Id*. at 168: 3-7.

121 *Id*. at 162: 18-24.

Entire Body of Evidence," in his capacity as a Wyeth sales representative.[122] More specifically, he recalled the "Body of Evidence" piece as a portion of Wyeth's Patient Action Center, which Wyeth describes as "a series of brochures designed to help you and your patient initiate a discussion about the consequences of menopause and its associated estrogen loss."[123] As Williams acknowledged, the Patient Action Center brochures discussed "Alzheimer's Disease, Vision Problems, Tooth Loss, Heart Disease, Colon Cancer, Urogenital Problems, and Osteoporosis," as health issues brought on by estrogen loss."[124] Mr. Williams also testified that he would stockpile these brochures in his storage locker as well as check to make sure the brochures were well stocked in doctor's offices.[125] Finally, Mr. Williams recalled that his detailing activities for the Premarin family of products would include discussing cardiovascular health with physicians.[126]

In another instance, Dr. Lal reviewed another Wyeth marketing piece, entitled "Hormone Replacement Therapy and Your Health," which Dr. Lal considered to be "one of the sources" of her understanding of the purported bone benefit of E+P[127] Dr. Lal also understood the piece was to be provided to the patient, as "sometimes it's hard to explain the whole thing to the patient."[128] Dr. Lal explained that she understood that the longer you stay on Prempro or Premphase, the longer a patient receives osteoporosis protection,"[129] which corresponds with the

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122 Ex. 93 - Deposition of Donald C. Williams II, 8/4/11 at 96:2-24 and 213:13-15.

123 *Id*. at 96: 2-24.

124 *Id*. at 100: 8-15.

125 *Id*. at 105: 4-13. Which corresponds to Dr. Lal's testimony that sales representatives would bring pamphlets with them during visits and leave the pamphlets with her office, including samples and booklets. Ex. 12 - Dr. Lal dep. at 160: 23-161: 12.

126 Ex. 93 - Mr. Williams dep. at 201: 13-15.

127 Ex. 12 - Dr. Lal dep. at 201:13-15.

128 *Id*. at 175: 18-176: 14.

129 *Id*. at 209: 23- 210:15.

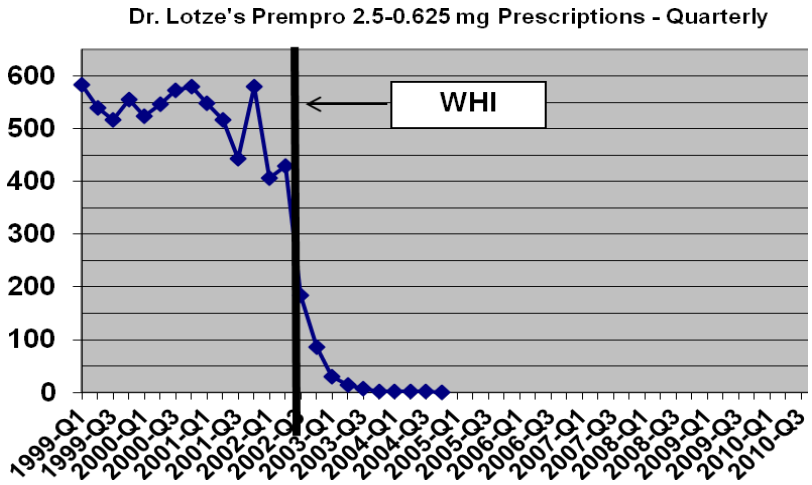
line contained in the marketing piece that read: "Bone protection continues only as long as you take Prempro."[130] Dr. Lal testified that this pamphlet was "one of the sources."[131]

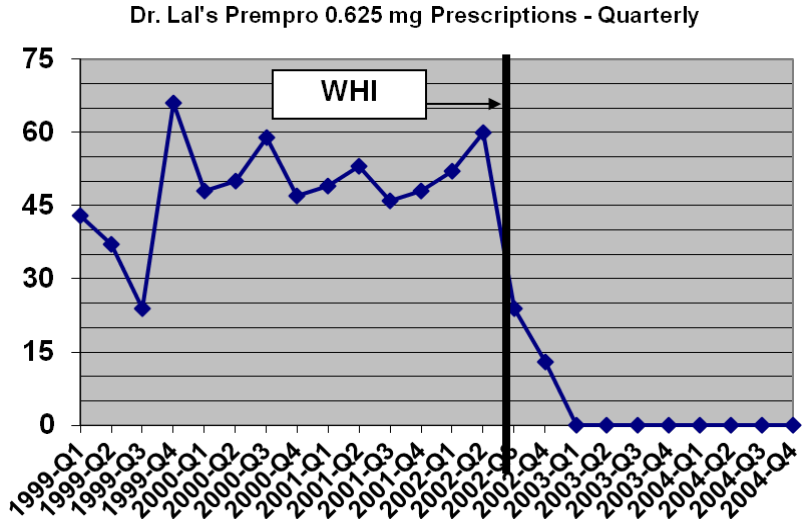
Drs. Lal and Lotze began counseling their patients differently after learning of the truth about E+P. Dr. Lal felt that plaintiff should have discontinued Premphase in light of the information now disclosed in the 2007 Prempro label,[132] adding that, had she known what is now reflected in the 2007 Prempro label concerning breast cancer risk, she would "asked if [Ms. Romero] could do without [E+P], or if she continued to have problems, maybe if she would have elected to have a hysterectomy, and [. . .] that way, we don't have to use progestin therapy along with estrogen."[133] In light of the WHI results, Dr. Lal began requiring patients sign an informed consent form prior to staying on Prempro.[134] Dr. Lotze's reaction to the WHI results were every bit as drastic as he stopped prescribing both "Prempro and Premphase,"[135] and advised those patients on the products to stop "Prempro and Premphase" and consider another compound.[136]

After WHI, when the truth was finally revealed, both doctors' prescription practices changed. Both Doctors have admitted that, after the WHI study, they prescribed the drugs less and discussed the new information with patients and switched patients off of E+P therapy. Objective evidence confirms both doctors' testimony. Wyeth purchases prescribing data from a

130 *Id*. at 203: 8-21.
131 *Id*. at 201: 13-15.
132 *Id*. at 232: 21-233:4.
133 *Id*. at 231: 19-232: 20.
134 *Id*. at 233: 5-10.
135 Ex. 92 - Dr. Lotze dep. at 206: 5-15.
136 *Id*. at 195: 16-197: 7.

tracking service called IMS. [137] When Wyeth produced such data in discovery, it showed that both doctor's prescriptions did plummet after the WHI was published.[138]





II. STANDARD OF REVIEW

The granting of summary judgment is inappropriate unless no reasonable trier of fact could find in favor of the nonmoving party.[139] Summary judgment may only be granted "if the

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[137] IMS Health, Inc. is an international company used by Wyeth and others to track prescription drug sales, including data specific to individual doctors. (*See, e.g.* http://www.imsgovt.com/Case/FDA.aspx, last visited April 7, 2011).

[138] Ex. 94 - IMS prescription data for Dr. Lotze's Prempro prescriptions; and IMS prescription data for Dr. Lal's Premphase prescriptions.

[139] *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 249 (1985).

pleadings [together with the] depositions [. . .] show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law."[140] If the moving party fails to meet its initial burden, the motion for summary judgment must be denied, regardless of the nonmovant's response.[141] In deciding a summary judgment motion, all reasonable inferences must be viewed in the light most favorable to the nonmoving party.[142] Even where the basic facts are undisputed, if reasonable minds could differ on the inferences to be drawn from those facts, summary judgment should be denied.[143]

III. ARGUMENT

A. Plaintiff's Failure-to-Warn Claim Must Proceed Beyond Summary Judgment.

As mentioned previously, this Court has already heard this issue, among others argued by Defendants in their motion, and held that summary judgment is not appropriate for this count or others in plaintiff's complaint, especially given the similar factual similarities between the *Lea* case and Mrs. Romero's case. In any event, Texas law does not support any basis for granting summary judgment in favor of the Defendants. Substantive evidence supports two exceptions to the Texas statutory FDA presumption against failure to warn claims.[144] They are (a) promotion of the drugs for unapproved indications and (b) withholding of material information from the FDA. Both exceptions apply here.

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140 FED. R. CIV. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

141 *Baton Rouge Oil and Chem. Workers Union v. ExxonMobil Corp.*, 289 F.3d 373, 375 (5th Cir. 2002).

142 *Calbillo v. Cavender Oldsmobile, Inc.*, 288 F.3d 721, 725 (5th Cir. 2002); *Anderson*, 477 U.S. at 255.

143 *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970)

144 *See* Tex. Civ. Prac. & Rem. Code § 82.007.

1. Texas' Statutory Presumption Does Not Apply Because Unapproved Indications Promoted by Wyeth Are Causally Related to Plaintiff's Injury.

a) Plaintiff Must Only Provide "Some Evidence" To Rebut the Statutory FDA Presumption.

As provided above, Texas recognizes several ways to rebut its statutory FDA presumption on failure to warn claims.[145] To interpret the underlying statute, the plain language of the statute controls, given ordinary meaning and as interpreted under the rules of grammar.[146] Based on the plain language of the statute, then, the following must be true:

(1) The statute only requires evidence that Wyeth promoted its drugs for off-label uses and such off-label uses are causally related to the plaintiff's use of that product and ultimate injury.[147]

(2) The unapproved indications need only be causally "related" to plaintiff's injury. The statute does not say they have to be a proximate or producing cause of the injury. *Id*. It simply has to be "related" causally. And Judge Englehart, the only Texas judge to evaluate this issue, agrees. Based upon a record almost identical to the one before this court, this Texas judge denied Wyeth's motion. In that case, after lengthy oral argument at which Wyeth made the same arguments expressed here, the trial court found that the Texas FDA presumption statute does not dictate summary judgment in a hormone therapy case.[148]

To overcome summary judgment, the plaintiff must simply set forth specific facts showing that there is a genuine issue of material fact for trial.[149] Presumptions simply shift the burden of producing evidence to the party against whom the presumption operates. The

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145 "(1) the Defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury" [. . .] "(3) (A) the Defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration; (B) the product was used as recommended, promoted, or advertised; and (C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product. TEX. CIV. PRAC. & REM. CODE § 82.007(b)(1) & (3)

146 Wyeth's motion at 14, n. 19, *citing* TEX. GOV'T CODE § 311.011(a)).

147 *See* Tex. Civ. Prac. & Rem. Code § 82.007(b)(3).

148 Ex. 95 - Orders in *Choueifati v. Wyeth*, 4/12/11.

149 *See Mossey v. City of Galveston, Tex.*, 94 F. Supp. 2d 793, 795 (S.D. Tex. 2000).

presumption disappears once any negating evidence is presented.[150] Importantly, Wyeth does not deny that it illegally promoted their hormone drugs for unapproved benefits. A plethora of evidence supports such a claim. The only question—a question for the jury—is whether belief in the unapproved benefits influenced Dr. Lal and/or Dr. Lotze's prescriptions or plaintiff's decision to ingest the drugs. As noted below, they did.

b) The Unapproved Indications that Wyeth Promoted to Physicians Are Causally Related to Plaintiff's Injuries.

The record is clear. Drs. Lal and Lotze were influenced by off-label promotion when prescribing E+P to plaintiff, especially with regard to a purported cardiac benefit associated with E+P. To begin with, both Doctors relied on drug companies—their sales representatives and marketing materials as well as medical journals—as sources of information concerning the risks and benefits of E+P. In no uncertain terms, Dr. Lotze testified that "drug detail people" played "no small role" in keeping him informed about prescription drugs. Dr. Lal was no different, relying on various sources of information from drug manufacturers when deciding to prescribe, including discussions with sales representatives as well as the materials each left behind. Both rely on drug companies to convey accurate information.

As Dr. Lotze testified, "we all thought, and we all counseled our patients, '[E+P] probably helps the heart.'" He also understood E+P to carry a mental benefit, including the prevention of Alzheimer's, which he used in his counsel of patients. Indeed, it was a Wyeth marketing piece, which refreshed his recollection as to a "general litany" of off-label benefits he believed to exist for E+P prior to WHI, including not only cardiac and mental benefits, but

[150] *See Ackermann v. Wyeth Pharms.*, 471 F. Supp. 2d 739, 749-50 (E.D. 2006), *aff'd*, 526 F.3d 203 (5th Cir. 2008); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 776 (S.D. Tex. 2008), *aff'd*, 321 Fed. Appx. 350 (5th Cir. 2009) (unpublished) (*cited in* Motion at 5 n. 2).

benefits addressing vision problems, tooth loss, colon cancer, urogenital problems and osteoporosis.

Dr. Lal, while aware of cardiac benefits of E+P, did not rely solely on those benefits when prescribing E+P. She did, however, rely on booklets and pamphlets distributed by Wyeth sales representatives to get a global understanding of E+P. One Wyeth sales representative who called on Dr. Lal, Donald C. Williams, II, remembered seeing a Wyeth marketing piece in his capacity as a Wyeth sales representative, which would include the time he detailed Dr. Lal. He remembered the piece was a part of the Wyeth's "Patient Action Center"—a series of brochures meant for prescribing physicians and patients, alike, to inform about the consequences of estrogen loss, including "Alzheimer's Disease, Vision Problems, Tooth Loss, Heart Disease, Colon Cancer, Urogenital Problems, and Osteoporosis." Mr. Williams stockpiled these brochures, making sure the doctors he detailed were well-stocked. Sure enough, his detailing activities for the Premarin family of products included a discussion of cardiovascular health with physicians. Finally, Dr. Lal recognized a Wyeth marketing piece, "Hormone Replacement Therapy and Your Health," as one of the sources informing her understanding of the purported bone benefit of E+P as well as a source provided to patients to assist in their understanding of the product. Her understanding of the E+P bone benefit reflects Wyeth's improper marketing mantra—bone protection continues only as long as you take Prempro.[151]

Consider the holding by the one court that has erroneously required advertising to be causally related to the plaintiff's injury, when the statute merely says the unapproved use must be causally related to that injury.[152] Even that court held that a plaintiff need only show the advertisements "influenced" the physician's decision to prescribe, not that advertisements were

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151 Ex. 12 - Depostion, Dr. Lal, *Romero v. Wyeth* at 203: 8-21.

152 *See Ebel v. Eli Lilly Co.*, 536 F. Supp. 2d 767 (S.D. Tex. 2008).

the only, or even the main, sources of information upon which the doctor relies.[153] Here, the promotion of off-label benefits clearly influenced both doctors' prescribing habits. That is all that is required to rebut the FDA presumption.[154]

2. The Statutory Presumption Does Not Apply Because Wyeth Withheld and Misrepresented Material Information to the FDA.

To begin with, this Court has already recognized that the same information now presented sufficed "to raise a fact issue regarding whether Wyeth withheld material information from the FDA."[155] When the FDA ordered Wyeth to incorporate the dramatically higher breast cancer risk associated with E+P versus E alone, Wyeth refused, going so far as to conceal data from the FDA to avoid strengthening its label. Finally, the label suggested that Wyeth's own clinical trial falsely showed only a risk of greater "detection" of breast cancer, even though the FDA told Wyeth to warn of a greater risk of "development" of breast cancer.

Wyeth also misrepresented to the FDA that its clinical trial on E+P reflected an incidence of breast cancer that was no different than the background rate. Wyeth was then successful at getting this reassuring language included in the breast cancer "warnings" section of its label for Prempro. Yet, Wyeth's own assessment confirmed that the E+P users in this study had a 47%

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153 *Id.* at 777.

154 Even if either doctor had testified expressly that he or she refused to rely on Wyeth's advertising (which neither does), their testimony would not entitle Wyeth to judgment as a matter of law. No witness' testimony is sacrosanct, particularly when it involves the witness's own state of mind. In the first two MDL trials, Wyeth moved for summary judgment on the learned intermediary defense, claiming the prescribing doctors' testimony established conclusively that they would have prescribed the drug even in the face of an adequate warning. The MDL court rejected this claim, in part based on its conclusion that a physician's hindsight testimony may serve as a basis for summary judgment, at most, only if it is self-disserving. *See In re Prempro Prods. Liab. Litig. (Rush v. Wyeth),* No. 05-CV00497, 2006 WL 1981902, at *3 (E.D. Ark. July 13, 2006); *See also In re Prempro Prods. Liab. Litig. (Reeves v. Wyeth),* No. 4:03CV00163, 2006 WL 1897267, at *3 (E.D. Ark. July 11, 2006). Courts consistently recognize that physicians have an interest in suggesting they were not wrong in the past and therefore might not be fully forthcoming regarding what they knew or relied upon in the past.

155 Ex. 1 - Lea, Order at 14.

increased risk of developing breast cancer than the incidence of breast cancer in the general population, as shown by the SEER data.[156] Wyeth falsely represented the results of this study, again identifying a lower risk than the product actually had.

In the summer of 2000, the FDA planned to modify much of the equivocal language of the Prempro label, remove the statement that the "effect of added progestins on the risk of breast cancer is unknown" and replace it with reference to epidemiological studies, which confirmed that combining E+P increased a woman's breast cancer risk by 25-40%.[157] On August 10, 2000, the FDA ordered Wyeth to reflect the data in its data. Rather than follow the FDA's order, Wyeth responded with a draft label even more reassuring than its then-existing label. Initially, Wyeth, proposed to highlight to the FDA an alarming finding by Dr. Gapstur that E+P conveyed a 4.42 relative risk for breast cancer with use of less than five years. Alas, Wyeth management saw to it that the 4.42 relative risk number was deleted, as well as any and all reference to the Gapstur study. Wyeth cherry-picked the data it wanted the FDA to have, not wanting the FDA to appreciate the Gapstur study's shocking elevated breast cancer statistic for E+P.

The United States Supreme Court found in *Wyeth v. Levine*,[158] that the amendments to the FDCA do not preempt state common law tort claims for failure to warn.[159] Moreover, the court in *Ackermann v. Wyeth Pharms.*, found that the exception in the Texas statute is not preempted.[160] Wyeth claims the *Ackermann* court's reasoning is based on its position that the

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156 Ex. 58 - PX 830 - at 18 (Overall, the incidence rate was 0.41 per 100 patient years in E+P users and 0.29 per 100 patient years from the SEER database placebo group giving a SJR=1.47(9500 CI, 0.47-3.43) (See Table 5, Appendix II)).

157 Ex. 65 - PX 20878.

158 *Wyeth v. Levine*, 129 S. Ct. 1187 (U.S. Mar. 4, 2009),

159 *Id.* at 1204.

160 471 F. Supp. 2d 739, 749-50 (E.D. Tex. 2006).

FDA presumption disappears with the production of evidence.[161] That is absolutely false. The court's reasoning is completely independent of its position on how the presumption is overcome. Like many other courts, the *Ackermann* court found that establishing a defense to a bar to recovery is not equivalent to a cause of action for fraud on the FDA that would interfere with the agency's operations. Proving the withholding of information does not entitle a plaintiff to recover damages. It simply gets plaintiff's feet into the courthouse.[162]

Wyeth relies heavily on *Lofton v. McNeil*, the recent Fifth Circuit opinion finding that § 82.007(b)(1) was preempted in a case in which the FDA expressly found that it had not been defrauded. *Lofton* is easily distinguished. In *Lofton*, the plaintiff claimed that the manufacturer withheld information from the FDA concerning adverse skin reactions to an over-the-counter product. A group unrelated to either *Lofton* party had already petitioned the FDA to change the label, alleging that the *Lofton* defendant withheld information concerning adverse reactions. The FDA responded, determining that: "[petitioners] provide no evidence to support this allegation. In addition, we have no evidence that there is additional undisclosed safety information that was withheld by the ibuprofen manufacturers." So, unlike the facts before this Court, the *Lofton* decision involved an express finding by the FDA that it had not been defrauded by that manufacturer concerning the product ingested by that plaintiff. No such finding exists, here.

3. Plaintiff Can Still Prove an Inadequate Warning if the Court Excludes Her Regulatory Experts' Failure-to-Test Opinions.

Again, this Court has every reason to follow the same reasoning it employed in the *Lea* case, and not exclude plaintiff's regulatory experts' failure-to-test opinions. However, it remains true that Drs. Blume and Parisian will testify on a broad range of liability issues, including the

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161 Wyeth's Motion at p. 10 n. 22).

162 *Ackermann*, 471 F. Supp. 2d at 749-50.

inadequacy of the Wyeth's labels based on the science of the time, consistent with their reports in this litigation. They will establish that Wyeth's representations about Premphase and Prempro were inadequate and false based upon what was actually known by Wyeth at that time as well as what Wyeth could have known if it had done the necessary studies. Plaintiff is not only arguing that Wyeth should have known more through testing, but that Wyeth's labels were inadequate based on the information available at the time.[163] Wyeth makes no argument as to why plaintiff's experts should not be allowed to testify about the inadequacy of the label based on what Wyeth already knew.

B. As a Matter of Law, Plaintiff's Defective Design Claim Must Prevail.

Wyeth's Motion for Summary Judgment on plaintiff's defective design claims should be denied since plaintiff establishes the existence of a safer alternative design to Prempro and Premphase. This Court has denied an identical motion by Wyeth.[164] Thus, as a matter of law, plaintiff's design defect claim.

1. Design Defect Claims Remain Viable in Texas.

In *Lea v. Wyeth,* this Court has already ruled that comment k did not bar that plaintiff's design defect claim, having considered identical arguments and evidence at this case.[165] Despite this, Wyeth simply re-states the same, arguing design defect claims are dead in Texas because

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163 Plaintiff's First Amended Complaint, paras. 83-84, 90, 92, 132, 145-146, 152.

164 Ex. 1 - *Lea* Order at 26. Both the MDL judge (Ex. 96 - Order by MDL Judge Wilson in *Reeves v. Wyeth* denying Wyeth's Motion for Summary Judgment, 8/23/06), and other federal judges (Ex. 97 - Order, 5/23/11, *Hines v. Wyeth, et al* ; Ex. 98 - Order in *Torkie-Tork v. Wyeth* by federal district judge Honorable T.S. Ellis denying Wyeth's Motion for Summary Judgment, 10/4/10) and state court judges (Ex. 99 - Trial transcript, *Singleton v. Wyeth*, 3/5/10 at p. 83:5-15) have denied identical motions by Wyeth and allowed this claim to go to the jury.

165 Ex. 1 - *Lea* Order at 26.

one federal district court said so.[166] This Court declined deciding the applicability of comment K, yet, the reason it declined to do so further supports sending plaintiff's design defect to the jury, as it found the evidence in *Lea*—which is substantively identical to that presented in this case—created "a fact issue as to the sufficiency of the warnings utilized by Wyeth."[167]

Further, as this Court recognized, Comment k exempts a product from strict liability claims only if the manufacturer's warnings were adequate, based on what the company knew *or should have known*.[168] Wyeth has presented no evidence defending the adequacy of their

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166 *See Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (Wyeth's Motion at p. 19). *Hackett* is an anomaly. Shortly before the court granted the defendant's motion for summary judgment, the court granted a motion by plaintiffs' counsel to withdraw and ordered the plaintiff to respond to defendant's motion *pro se*. The plaintiff filed no response and the motion for summary judgment was granted. The issue of comment k's scope was never litigated. Ex. 107 - Order, *Hackett v. G.D. Searle & Co.*, Case No. A-01-CA-399-SS (W.D. Tex. Mar. 18, 2002). No Texas state court has ever cited *Hackett* with approval. Many Texas courts have recognized the viability of design defect claims in pharmaceutical cases: *See, e.g., Madden v. Wyeth*, 2005 WL 2278081, at *2 (N.D. Tex. Sept. 14, 2005) (denying motion for summary judgment on design defect claim based on Children's Advil three years after *Hackett*); *Boswell v. Burroughs Welcome Co.*, 1997 WL 198746, at *2 (Tex. App.--Dallas 1997, pet. denied) (acknowledging design defect claim as one of three strict liability claims available in a pharmaceutical case) (not designated for publication).

167 Ex. 1 - *Lea* Order at 25. Still, the majority of courts have determined the applicability of comment k must be determined on a case-by-case basis. *See Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003); *see also Weiss v. Fujisawa Pharm. Corp.*, 2006 WL 3533072, at *3 (E.D. Ky. Dec. 7, 2006) ("this Court agrees with the majority position that the case-by-case analysis is better supported by the language of comment k"); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000) ("The majority of jurisdictions that have adopted comment k apply it on a case-by-case basis."); *accord Savina v. Sterling Drug Co.*, 195 P.2d 915, 924 (Kan. 1990). Perhaps most telling is the fact that the American Law Institute, in drafting comment k, considered adopting blanket immunity against prescription drug claims but rejected the suggestion. *See West v. Searle & Co.*, 806 S.W.2d 608, 612 (Ark. 1991); *see also Hill v. Searle Labs*, 884 F.2d 1064, 1069 (8th Cir. 1989).

168 Ex. 1 - *Lea* Order at 25-26. *See Kociemba v. Searle & Co.*, 680 F. Supp. 1293, 1300-01 (D. Minn. 1988); *Martinkovic v. Wyeth*, 699 F. Supp. 212, 216 (N.D. Ill. 1987); *see also White v. Wyeth*, 1987 WL 14953, at *4 (Ohio App. 1987).

warnings. And, as in *Lea*, plaintiff's experts have testified that the warnings were inadequate.[169] The adequacy of the warnings is a question of fact for the jury.[170]

2. Plaintiff's Suggested Modifications Would Create Safer Alternate Designs.

Viewing much the same evidence as now, this Court found that Jean Lea's suggested modification to Wyeth's E+P sufficient to defeat summary judgment as to her design defect claim.[171] As in *Lea*¸ plaintiff advocates a low-dose form of Wyeth's combination product as one of her safer alternative designs. Wyeth offers no reason why the Court should overrule itself.

Wyeth notes that an alternative design must be a product modification and cannot involve the creation of a new product that lacks the features of the old product. But plaintiff advocates modifications to E+P, the product at issue. After all, physicians prescribed progestins, natural or synthetic, with estrogen purely to reduce the risk of endometrial cancer caused by unopposed estrogen therapy.[172] Progestin is essentially the safety guard of the product. The benefits of the drug come from E alone. Plaintiff argues that changing the safety mechanism from synthetic to natural progesterone makes the product even safer. This is no different than changing a plastic safety guard to a metal one to increase product safety. Similarly, reducing the dose of hormones

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169 Plaintiffs' experts have testified that the warnings were inadequate - Ex. 100 - Trial testimony, Suzanne Parisian, *Scroggin v. Wyeth*, 2/12/08 at 1345:1-23; 1303:16-20; Ex. 101 - Trial testimony, Suzanne Parisian, *Singleton v. Wyeth*, 1/27/10 at 102:17-127:3; Ex. 62 - Trial testimony, Suzanne Parisian, *Torkie-Tork v. Wyeth*, 11/22/10 at 90:5-91:2; 91:4-97:20 (dose and duration); 97:21-98:2 (majority of studies); 98:3-21 (adding progestins); 98:22-100:25 (Wyeth's one-year clinical trial); 101:7-103:14 (PEPI); 51:3-53:7; 59:1-18 (lean women).

170 Ex. 1 - *Lea* Order at 26. *See also Alm v. Aluminum Co. of America*, 717 S.W.2d 588, 592 (Tex. 1986).

171 Ex. 1 - *Lea* Order at 27.

172 Ex. 102 - PX MA 2216 - R. D. Gambrell et al., *Use of the progestogen challenge test to reduce the risk of endometrial cancer,* 55 No. 6 OBSTETRICS & GYNECOLOGY 732-38 (Jun. 1980); Ex. 103 - PX MA 3 - R. Greenblatt, *The estrogen-cancer controversy*, No. 28 J. AM. GERIATRIC SOC. 1-8 (1978).

in E+P certainly does not create a new product, any more than 81 milligrams of aspirin is a different product than 325 milligrams of aspirin.

Wyeth has presented no evidence that either design change would fundamentally alter the functioning of the drugs so as to constitute a new product rather than a safer alternate design.[173]

As in *Lea*, Wyeth cites decisions in the pedicle screw litigation holding that different products to address the same condition – products that do not contain screws – do not constitute alternate designs.[174] But here, both alternatives plaintiff proposes include estrogen and progestin with one including a different type of progestin and the other involving different levels of estrogen and progestin for short duration use.

Wyeth again contends that the decision in *Brockert v. Wyeth*[175] is applicable.[176] *Brockert* is inapposite since that plaintiff did advocate a different product—specifically, she advocated

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173 As Judge Ellis wrote regarding both designs:

> As to the first proposed alternative design, it may well be that the dosage of a drug is a fundamental characteristic of the drug, since a lower dosage may well alter or affect the positive impact the drug is designed to have on the human body. In her brief, plaintiff offers little explanation for the costs and benefits of a change in the dosage of Prempro, if such an analysis is even feasible with the current science available. Nevertheless, the decision properly rests with a jury to determine whether an alternative dosage of Prempro would so fundamentally alter the drug as to render it an entirely different product. Plaintiff's second proposed alternative design similarly presents an issue of fact properly submitted to a jury. If Wyeth could have used a natural progesterone instead of synthetic progestin and accomplished a similar positive therapeutic effect, a jury may reasonably decide that the refusal to employ such a design was negligent. On the other hand, Wyeth may martial evidence to show that this proposed alternative design would fundamentally alter Prempro, in which event a jury might reasonably conclude that such an alteration would result in a wholly different product-Prempro would no longer be Prempro, much as a four-wheel vehicle with a cab would cease to be a motorcycle. In short, on this issue-alternative design-the summary judgment record presents a genuine issue of fact for trial.

Torkie-Tork, 739 F. Supp. 2d at 900-01.

174 Wyeth's Motion at p. 20-21.

175 *Brockert v. Wyeth*, 287 S.W.3d 760 (Tex. App.—Houston [14th Dist.] 2009, no pet.).

176 Wyeth's Motion at pp.31-32.

Premarin, Prempro's predecessor, as a safer alternative design to Prempro. This meant removing any protection from endometrial cancer. Here, though, plaintiff merely offers different designs of the same product, not a different product. If Wyeth contends that the modifications suggested would create a product with different effects, it is incumbent on Wyeth to show that, but Wyeth is not entitled to summary disposition on the mere assertion.[177]

C. Plaintiff has Demonstrated Sufficient Evidence as Basis for Recovery of Exemplary Damages

As this Court set forth in *Lea*, "Summary Judgment is 'generally inappropriate where inferences parties seek to draw deal with questions of motive and intent."[178] The same evidence plaintiff now presents was found sufficient to create a general issue of material fact as to Wyeth's fraudulent intent, yet Wyeth offers no reason why the Court should find differently in this case.[179] Indeed, plaintiff presents the Court with the exact same evidence that the Court

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[177] *Brockert*, at pp. 770-71. As Judge Ellis wrote:

> [T]he analysis in *Brockert v. Wyeth* is distinguishable from the present case. 287 S.W.3d 760, 769 (Tex.App.Ct.2009). There, a state appellate court in Texas upheld the grant of summary judgment to Wyeth on a negligent design defect claim. The plaintiff in *Brockert* contended that the safer alternative design of Prempro would have been estrogen alone, and the Texas court recognized that such a design would essentially mean that "Prempro should have been a different product[,] [namely] its predecessor[,] Premarin." *Id.* at 769-71. Here, plaintiff argues that an alternative dosage formulation or a substitution of progestin with its natural counterpart would have been safer; whether such changes would fundamentally transform Prempro into a completely different product is a genuine issue of fact appropriate for jury resolution.

Torkie-Tork, 739 F. Supp. 2d at 901 n. 8 (brackets in original).

[178] Ex. 1 - *Lea* Order at 31 (citing *Williams v. Upjohn Co.*, 153 F.R.D. 110, 116 (S.D. Tex. 1994).

[179] Plaintiff also notes that appellate courts around the country have upheld jury verdicts awarding punitive damages against Wyeth in hormone therapy litigation. *See Kendall v. Wyeth, Inc*., 2012 WL 112609 at 24 (Pa. Super 2012); *Barton v. Wyeth, Inc.*, 2012 WL 112613 at 22 (Pa. Super. 2012) (entering remittitur); *Daniel v. Wyeth, Inc.*, 15 A.3d 909, 935 (reinstating jury verdict awarding punitive damages); and *Wyeth v. Rowatt*, 244 P.3d 765, 786 (Nev. 2010).

found to create a fact issue regarding Wyeth's intent.[180] Wyeth's only support is a vague reference to an FDA committee that, prior to approving Prempro, found information about breast cancer to be inclusive. This lone example cannot survive even the slightest scrutiny, as this Court has previously found that sufficient evidence against Wyeth exists to support a "fraud-on-the-FDA" rebuttal to the statutory presumption in § 82.007.[181]

IV. CONCLUSION

For the foregoing reasons, plaintiff respectfully requests that Wyeth's Motion be denied and that plaintiff be awarded all other relief to which she is entitled.

Dated this 16th day of March, 2012.

Respectfully Submitted,

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[180] The Court explained that "several memoranda highlight the company's goal to 'undermine/cast doubt on [the] validity of [the] data" and communicate that there was "no definitive answer regarding [HRT's] impact on breast cancer." *Lea v. Wyeth, et. al*, No. 1: 03-CV-1339 (E.D. Tex. Oct. 28, 2011) (brackets in original). The same memoranda that the Court references are included in this response. *See supra* at 6-23 and 33-35.

[181] Ex. 1 - *Lea* Order at 16.

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CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of March, 2012, a true and correct copy of the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system, and notification was sent to the parties below:

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